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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,879	09/09/2003	Nila A. Shah	3517.1	3228

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EXAMINER	
PATEL, SHAMBHAVI K	
ART UNIT	**PAPER NUMBER**
2128	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/658,879	SHAH ET AL.	
	Examiner	Art Unit	
	Shambhavi Patel	2128	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 September 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/9/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-20 are pending.

Priority

2. Acknowledgment is made of applicant's claim for priority to provisional applications 60/409,396 filed on 09/09/02 and 60/409,800 filed on 9/11/02.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 28 June 2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the Examiner has considered the IDS as to the merits.

Drawings

4. The drawings are objected to because they are not numbered. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claims 1-5 and 16-20 are rejected under 35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding **claim 1**, the term "useful" is a relative terms that render the claim indefinite. The term "useful" is not defined by the claims, the specification does not provide a standard for ascertaining the relative degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Regarding **claim 16**, the contents of the "instruction computer file" is unclear. The Examiner interprets the file to be a computer instruction file that provides instructions for synthesis of an array comprising said design. All other claims are rejected by virtue of their dependency.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. **Claims 1, 3-5, 6, 8-10, 12-15 and 16-20 are rejected under 35 U.S.C. 103(a)** as being unpatentable over **Chee (US Publication No. 2002/0025520) in view of Hubbell (US Patent No. 5,593,839).**

Regarding claim 1:

Chee discloses a computerized method for designing a resequencing array to resequence a user selected sequence **(abstract)** comprising:

a. receiving a user design request comprising a user selected sequence **([0024])**. The selection of the sequence from the database is inherently done by a user.
b. producing an array design for resequencing said user selected sequence **([0020])**
c. outputting said array design to said user and receiving acceptance for said array design from said user **([0016])**. The resequencing array is not accepted until the reestimate sequence of the target nucleic acid is the true sequence of the target nucleic acid.
d. outputting a file that is useful for controlling a nucleic acid synthesizer during the construction of an array comprising said design **([0044])**. Chee discloses the VLSIPS synthesis method and the use of an inkjet printer to synthesize the array. Both of these methods inherently utilize a file in order to construct the array.

e. synthesizing at least one copy of said array and providing said at least one copy of said array to said user **([0044]-[0045])**.

Chee does not explicitly disclose the use of a file providing instructions to a nucleic acid synthesizer for synthesis of an array comprising said design. **Hubbell teaches** using a computer (and thus computer design files) to synthesize the array **(Hubbell: abstract; column 10 lines 42-59).** At the time of the invention, it would have been obvious to one of ordinary skill in the art to combine the teachings of Chee and Hubbell because the computer system taught by Hubbell provides *improved sequence and mask generation techniques*, especially computer tools for forming arrays of materials such as nucleic acids **(Hubbell: column 2 lines 11-16).**

Regarding claim 3:

Chee discloses a user design request comprising a sequence file **([0024]).**

Regarding claim 4:

Chee discloses receiving the request over the Internet **([0024]).** The sequences are obtained by accessing the Genbank database, which is available at the website provided.

Regarding claim 5:

Chee discloses user selected control probes **([0045]).**

Regarding claim 6:

Chee discloses a method for a provider of nucleic acid arrays to provide a user with an array for resequencing a user selected nucleic acid **(abstract)** wherein the method comprises:

a. receiving a sequence computer file from said user wherein the sequence computer file comprises the sequence of the user selected nucleic acid **([0024])**. The selection of the sequence from the database is inherently done by a user.

b. preparing a design for a resequencing array for the selected sequence **([0020])**

c. outputting said design into a file, providing said file to said user and receiving approval for said design from said user **([0016])**. The resequencing array is not accepted until the reestimate sequence of the target nucleic acid is the true sequence of the target nucleic acid. A file would inherently be used to store the design.

d. synthesizing said array and providing said user with said array **([0044]-[0045])**.

Chee does not explicitly disclose the use of instruction computer files providing instructions to a nucleic acid synthesizer for synthesis of an array comprising said design. **Hubbell teaches** using a computer (and thus computer design files) to synthesize the array **(Hubbell: abstract; column 10 lines 42-59)**. At the time of the invention, it would have been obvious to one of ordinary skill in the art to combine the teachings of Chee and Hubbell because the computer system taught by Hubbell provides *improved sequence and mask generation techniques*, especially computer tools for forming arrays of materials such as nucleic acids **(Hubbell: column 2 lines 11-16)**.

Regarding claims 8-9:

Chee discloses the method of claim 6 wherein said provider has computer-executable code that identifies ambiguous sequence within said user selected nucleic acid sequence by: obtaining analogous sequence from at least one other source; comparing the sequence from said file to said sequence from at least one other source; identifying bases that are different and removes ambiguity by comparing the sequence from two or more sources **([0037])**.

Regarding claim 10:

Chee discloses the method of claim 6 wherein said provider also provides said user with the sequence of primers that may be used to amplify said user selected sequence **([0027])**.

Regarding claim 12:

Chee discloses the method of claim 6 wherein said user selected sequence is identified by said user in an association study or a linkage study wherein said sequence is associated with a phenotype **([0006])**. Chee discloses array-based resequencing which has been used in the analysis of mutations in p53 correlated with human cancer (i.e. a disease related study).

Regarding claim 13:

Chee discloses the method of claim 6 wherein said user first identifies said user selected sequence as being associated with a phenotype using a genotyping array that genotypes more than 10,000 different human polymorphisms **([0012], [0018])**.

Regarding claim 14:

Chee discloses receiving the request over the Internet **([0024])**. The sequences are obtained by accessing the Genbank database, which is available at the website provided.

Regarding claim 15:

Hubbell discloses the production of a file containing a description of the probes that can easily be used by anyone who creates DNA chips, runs experiments on chips, or analyzes the data created from the experiment **(column 13 lines 19-30)**. It would have been obvious to a skilled artisan to send these files to users over the Internet because this is widely practiced in the art.

Regarding claim 16:

Chee discloses

a. using a computer to design one or more resequencing arrays for one or more regions of a genome of interest **(abstract)**

b. receiving an order from a user for a specific design for an array to resequence a selected sequence **([0024])**. The resequencing array is not accepted until the reestimate sequence of the target nucleic acid is the true sequence of the target nucleic acid. The repetition of the steps is optional, and the user can decide what level of accuracy is needed.

c. synthesizing the array **([0044]-[0045])**.

Chee does not explicitly disclose providing users with a list of available designs, outputting a computer instruction file and synthesizing the array using said instruction computer file. **Hubbell teaches** providing available designs to a user **(column 2 lines 16-22)**, outputting a computer instruction file that can be used to synthesize the array **(Hubbell: abstract; column 10 lines 42-59).** At the time of the invention, it would have been obvious to one of ordinary skill in the art to combine the teachings of Chee and Hubbell because the computer system taught by Hubbell *provides improved sequence and mask generation techniques*, especially computer tools for forming arrays of materials such as nucleic acids **(Hubbell: column 2 lines 11-16)**.

Regarding claim 17:

Chee discloses the method of claim 16 wherein said provider also provides said user with the sequence of primers that may be used to amplify said user selected sequence **([0027])**.

Regarding claim 18:

Chee discloses the method of claim 16, wherein said genome of interest is the human genome **([0017]).**

Regarding claim 19:

Chee discloses the method of claim 16 wherein said selected sequence comprises at least one complete chromosome **([0018]).**

Regarding claim 20:

Hubbell discloses the production of a file containing a description of the probes that can easily be used by anyone who creates DNA chips, runs experiments on chips, or analyzes the data created from the experiment **(column 13 lines 19-30).** It would have been obvious to a skilled artisan to send these files to users over the Internet because this is widely practiced in the art.

7. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chee (US Publication No. 2002/0025520) in view of Hubbell (US Patent No. 5,593,839) in view of Quate (US Patent No. 6,480,324)

Regarding claim 2:

Chee does not explicitly disclose a maskless synthesizer. **Quate teaches** polymer array synthesis by utilizing a maskless optical lithography system **(Quate: column 3 lines 25-27).** At the time of the invention, it would have been obvious to one of ordinary skill in the art to combine the teachings of Chee, Hubbell and Quate because the maskless synthesizer improves the cost, quality, and efficiency of polymer array synthesis **(Quate: column 3 lines 22-26).**

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chee (US Publication No. 2002/0025520) in view of Hubbell (US Patent No. 5,593,839) in view of Nelson ("Negative Selection: A Method for Obtaining Low-Abundance cDNAs Using High-Density cDNA Clone Arrays"):

Regarding claim 7:

Chee does not explicitly disclose removing repetitive sequences. **Nelson teaches** removing repetitive sequences **(Nelson: "Introduction" 3rd paragraph)** using RepeatMasker **(Nelson: section 2.3 2nd paragraph).** At the time of the invention, it would have been obvious to one of ordinary skill in the art to combine the teachings of Chee, Hubbell and Nelson because since repetitive sequences are not useful for database homology searches and add little information, it would be desirable to remove the clones **(Nelson: "Introduction" 3rd paragraph).**

9. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chee (US Publication No. 2002/0025520) in view of Hubbell (US Patent No. 5,593,839) in view of Kulp (US Publication No. 2002/0183936):

Regarding claim 11:

Chee does not explicitly disclose the use of a GUI to allow users to buy primers. **Kulp teaches** a web portal that provides genomic data to a user through a GUI **(Kulp: [0101]).** At the time of the invention, it would have been obvious to one of ordinary skill in the art to combine the teachings of Chee, Hubbell and Kulp because the web portal provided improved tools and information to provide much needed information to researchers **(Kulp: ([0006]).**

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shambhavi Patel whose telephone number is (571) 272-5877. The examiner can normally be reached on Monday-Friday, 8:00 am – 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kamini Shah can be reached on (571) 272-2279. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKP